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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/677,767	10/02/2003	Robert Harris	DIA 1809-002B	9126

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EXAMINER

KIM, YUNSOO

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 06/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/677,767

Applicant(s)

HARRIS ET AL.

Examiner

Yunsoo Kim

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) 3-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 2 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 10/13/04, 1/10/06
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. Claims 1-13 are pending.
2. Applicant's election without traverse of Group I, drawn to claims 1-2, a method to stimulate immune system, in the reply filed on 3/6/06 is acknowledged.

Claims 3-13 are withdrawn from further consideration by the examiner, 37 C.F.R. § 1.142(b) as being drawn to a nonelected invention. Claims 1-2 are under consideration in the instant application.

3. Applicants' claim for domestic priority under 35 U.S.C. 119(e) is acknowledged.
4. Applicants' IDS filed on 10/13/04 and 1/10/06 have been acknowledged.

However, the US Pat 4,473,495, and the references under other documents, 2, 5 and 6 of the IDS filed 1/10/06 have been crossed out as being duplicates of the references in the IDS filed 10/13/04. The references 3, 4 and 8 of the IDS filed 1/10/06 have been lined through for missing authors. In addition, the foreign documents in IDS filed 1/10/06 have not been considered as Applicants failed to provide copies of the references. Furthermore, the reference 7 under the IDS filed 1/10/06 has been considered but crossed off as it is not appropriate for an information disclosure. In addition, the reference 9 of the IDS filed 1/10/06 has not been considered as being non-English literature.

5. The specification is objected to because of the following informalities:
The Description of Figure is required for Figure 1 in the specification.
6. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The specification should be amended to included "a method to stimulate immune system in vitro with an antigen" in claim 1 and "a method to modulate an undesired current status of immune system" in claim 2.
7. It is noted that the date of execution of the oath by the first inventor is missing. However, an oath is no longer considered defective for lack of a date.

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8. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

9. Claims 1-2 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-2 of copending Application No. 10/806,358. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 1 and 2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(A) The phrase “the immune system *in vitro*” recited in claim 1 is ambiguous and unclear as the method teaches the administering of an antigen. In addition, the immune system includes the integrated body system of organs and tissues and it is not clear how the immune system is limited to *in vitro*.

(B) The phrase “the current preprogrammed response” does not define metes and bounds of the invention. The specification of the instant application fails to define current or preprogrammed. The terms are relative and the reference point needs to be defined.

(C) The term “modulate” or “immunomodulation” recited in claim 2 is ambiguous and unclear as the direction of modulating may be either “stimulatory or suppressive”, “faster or slower” or “on or off”.

(D) The phrases “undesired current status” and “unwanted immune response” recited in claim 2 do not define metes and bounds of the invention.

(E) The phrase “immunoneutral formulation” in claim 1 is not defined and it is unclear what the immunoneutral formulation” encompasses. The instant specification provides a single HSA being immunoneutral but no definition (p. 4, [017]).

(F) Claim 2 is rejected under 35 U.S.C. 112, second paragraph as being incomplete for omitting essential steps, such omission accounting to a gap between steps. See MPEP 2172.01. While all the technical details of a method need not be recited, the claim should include enough information to clearly and accurately describe the invention and how it is to be practiced.

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The instant claim is drawn to a method for modulating an undesired current status of the immune system in an individual. It is not clear how the method of modulating an undesired current status is being achieved by the evaluating the immune response to an antigen and deciding the therapeutic formulation suitable for specific modulation.

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S.Pat. No. 6,093,396.

The '396 patent teaches a method to stimulate immune system *in vitro* with an antigen (an immunoprecipitation of modified hGAD65 and sera from both IDDM and healthy individuals, Example 3, col. 5, lines 40-55). The immunoreactivity of modified hGAD65 was monitored by the immunoprecipitation of higher radioactive antibodies in diabetic individuals and is considered by the stimulation of immune system *in vitro* by modified hGAD65.

The '396 patent further teaches a method for administering modified hGAD65 in immunological neutral formation (i.e. non-specific serum albumin in saline) for treating autoimmune diseases, IDDM (i.e. undesired/ unwanted status, col. 3, lines 23-47, col. 5, line 42-55). The '396 patent further teaches modified hGAD65 is useful as an immunomodulant therapeutic to prevent certain autoimmune diseases (col. 4, lines 1-44).

In light of the specification [0002], GAD is defined as a major antigen and [0031] defines human serum albumin as an immunoneutral protein. Furthermore, the specification does not define "preprogrammed response", "undesired current status" or "unwanted immune response", those claimed limitations are interpreted as diseased condition as GAD associated with autoimmune diseases.

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As taught by the Example 3, the immune system *in vitro* was stimulated by the modified hGAD65 (e.g. antigen), the antigen was administered to human to treat or prevent autoimmune diseases (e.g. modulating away the unwanted status) (claims 9-10). Thus, the reference teachings anticipate the claimed invention.

14. No claims are allowable.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yunsoo Kim whose telephone number is 571-272-3176. The examiner can normally be reached on Monday thru Friday 8:30 - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Yunsoo Kim
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May 11, 2006


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